IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bohn, et al

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USE OF 1-HYDROXY-2-PYRIDONES FOR THE TREATMENT OF SEBORRHEIC DERMATITIS

DECLARATION OF JAMES LEYDEN, M. D.

I, James Leyden, M.D., do hereby declare that:

1. My B.A. in Biology is from St Joseph's College (1962) and I obtained my M.D. from the University of Pennsylvania in 1966. I did my residency at the University of Pennsylvania.

2. I am a practicing dermatologist and have been so since 1972. I have held the following positions: Assistant, Associate Professor and Professor of Dermatology at the University of Pennsylvania, School of Medicine. I am currently an Emeritus Professor of Dermatology at the University of Pennsylvania, School of Medicine.

3. Over the years, I have authored numerous articles and books on dermatology, including several on the subject of scaling disorders of the scalp including the etiology of these disorders. My professional achievements include positions on the editorial boards of the Journal of the American Academy of Dermatology, and Skin and Aging among others and Editor-in-Chief of Cutaneous Aging and Cosmetic Dermatology. A copy of my CV is attached hereto as Exhibit A.

4. In my practice, I have treated numerous patients suffering from seborrhea and others suffering from seborrheic dermatitis. All of the following has been known to dermatologists since at least 1997.

5. Seborrhea is a condition of the sebaceous glands characterized by the excessive production of sebum by the sebaceous glands which, when it reaches the skin surface, makes the skin appear oily or shiny and feel greasy. Seborrhea does not involve the skin's keratinocytes, and does not cause seborrheic dermatitis.

6. Seborrheic dermatitis is not a condition of the sebaceous glands. *See* Fitzpatrick's Dermatology in General Medicine, 6th ed., p. 1198 (attached hereto as Exhibit B). It is a chronic papulosquamous dermatosis (*see* Ex. B, p. 1198), and a disorder characterized by the hyperproliferation of keratinocytes in the skin. It is characterized by erythema (redness of the skin), scaling and yellow crusted patches. See Ex. B, p. 1198-1199. The origin of the name, seborrheic dermatitis, is that the disorder is most prevalent in areas where there are high densities of sebaceous glands (e.g. face and ears), not because sebaceous glands, sebum or seborrhea are related to the disorder. Essentially, in seborrheic dermatitis, the epidermal keratinocytes multiply too quickly, causing scaling and other symptoms. The sebaceous glands are not involved in seborrheic dermatitis and excess sebum production is not a diagnostic feature of seborrheic dermatitis.

7. Seborrhea is not a subset of seborrheic dermatitis, nor is seborrheic dermatitis a subset of seborrhea. Seborrhea and seborrheic dermatitis are different disorders and involve different cells: the sebaceous glands (seborrhea) and the keratinocytes (seborrheic dermatitis).

8. It is well-known among dermatologists that not every seborrhea patient has seborrheic dermatitis. Conversely, it is well-known among dermatologists that not every seborrheic dermatitis patient has seborrhea. From my dermatology practice and years as a teacher and researcher in this field, it is apparent that seborrheic dermatitis is very common in older patients, most of whom do not have seborrhea. This would be known to any dermatologist. Fitzpatrick concurs stating, "an increased sebum production cannot always be detected in [seborrheic dermatitis] patients," and "seborrheic dermatitis is not a disease of the sebaceous glands." *See* Ex. B, p. 1198. Other treatises reflect this view.

9. U.S. Patent No. 4,172,149 (filed in 1978, and attached hereto as Exhibit C), states that seborrhea (or excessive sebum) is "one component of the pathology [of seborrheic dermatitis]." This is wrong. It does not reflect the understanding of practitioners in this field.

10. U.S. Patent No. 6,120,756 states that seborrheic dermatitis "as used herein is defined as chronic inflammatory disease of the skin associated with excessive sebum production," (Col. 6, Lines 30-32, attached hereto as Exhibit D.) While this patent may so define this term for its own purposes, that doesn't reflect the understanding of the art, i.e., it is wrong. *See* Ex. B. Seborrheic dermatitis is a chronic inflammatory disease of the keratinocytes but it is not associated with excessive sebum production. *See* Ex. B, p. 1198-1199. Many, if not most, patients with seborrheic dermatitis do not have excessive sebum production. In fact, there is no evidence that seborrheic dermatitis is associated with either increased or decreased sebum production.

11. Because seborrhea and seborrheic dermatitis are totally different disorders, a dermatologist would not normally use an anti-seborrheic agent (that is, an agent used to treat seborrhea) to treat seborrheic dermatitis. This is especially true because dermatologists often see seborrheic dermatitis in patients who don't have seborrhea, and therefore know that seborrhea is not a subset nor the same as seborrheic dermatitis and seborrheic dermatitis is not a subset of seborrhea. Put another way, a physician will not use a treatment for seborrhea in connection with a disorder, such as seborrheic dermatitis, which is known to be different in both cause and effect from seborrhea.

All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any registration resulting therefrom.

Date: 1/4/06

James Leyden, M.D.

CURRICULUM VITAE

James J. Leyden, M.D.

Personal Data:

Full Name:	*James Joseph Leyden*
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Date of Birth:	*August 20, 1940*
Place of Birth	*Philadelphia, Pennsylvania*
Citizenship:	*United States of America*
Marital Status	*Married - December 27, 1962* *Wife: Claudette Schilling* *Children: Wendy and James*

Education:

1958-1962	*A.B. Saint Joseph's College*
1962-1966	*M.D. University of Pennsylvania School of Medicine*

Postgraduate Training and Fellowship Appointments:

1966-1967	*Intern Temple University Medical School*
1967-1968	*Resident in Dermatology, University of Pennsylvania*
1967-1968	*United States Public Health Fellow*
1970-1972	*Resident in Dermatology, University of Pennsylvania*

Military Service:

1968-1970	*Chief of Dermatology, U.S. Army, Fort Devens*

Editorial Positions:

1985-1990	*Editorial Board, Journal of the American Academy of Dermatology*
1987-1992	*Editorial Board, Journal of Microbial Ecology in Health and Disease*
1988-1992	*Editorial Board, Medicine Group*
1988-1992	*Editor-in-Chief, Cutaneous Aging and Cosmetic Dermatology*
1993-	*Editorial Advisory Board, Skin & Aging*

Committees:

1993-1997	*American Academy of Dermatology, Board of Directors*
1989-2001	*Dermatology Foundation, Chairman, Board of Trustees*
1987-	*Executive Committee, Dermatology Foundation*
1988-1989	*Vice President, Dermatology Foundation*
	American Academy of Dermatology Infectious Disease Committee Chairman
	American Academy of Dermatology Health Industry Liaison Committee, Chairman
	American Academy of Dermatology Task Force On Steroid Anti-infection Agents, Vice Chairman
	American Academy of Dermatology Government Liaison Committee
	American Academy of Dermatology Therapeutics Committee
	Toxicology Committee, National Academy of Sciences
	Consultant to U.S.A. FDA and FTC
	Consultant to Health Protection Branch
	Canada Consultant to Drug Regulation Agencies of England, Germany, and Austria
1988-2002	*Admissions Committee, School of Medicine, Medical Audit Committee, Hospital of the University of Pennsylvania Utilization Review Committee, Hospital of the University of Pennsylvania*
2003-	*Sub-committee on Acne Management, American Academy of Pediatrics*

Faculty Appointments:

1972-77	*Assistant Professor of Dermatology, University of Pennsylvania School of Medicine*
1972-87	*Chief of Dermatology Clinic, Hospital of the University of Pennsylvania*
1977-83	*Associate Professor of Dermatology, University of Pennsylvania School of Medicine*
1979-	*Affiliated Senior Scientist, Monell Chemical Senses Center*
1983-	*Professor of Dermatology, University of Pennsylvania School of Medicine*
2002	*Professor Emeritus, University of Pennsylvania School of Medicine*
2002	*Adjunct Professor of Dermatology, Northwestern University School of Medicine*

Specialty Certification:

1973	*American Board of Dermatology*

Licensure: *Pennsylvania*

Awards, Honors, and Membership in Honorary Societies:

1962	*Who's Who of American Colleges*
1966	*Alpha Omega Alpha (Honorary Medical Society)*
1971	*Henry W. Stelwagon Award American Academy of Dermatology*
1972	*North American Dermatological Association Award*
1976	*Bronze Award for Original Investigation American Academy of Dermatology*
1985	*Gold Award for Original Investigation American Academy of Dermatology*
1986	*Bronze Award for Original Investigation American Academy of Dermatology*
1986	*Silver Award, Teaching Value American Academy of Dermatology*
1997	*Gold Award for Original Investigation American Academy of Dermatology*
2003	*Honorary Member, Society of Investigative Dermatology*

Memberships in Professional and Scientific Societies:

Society of Investigative Dermatology
American Academy of Dermatology
Infectious Control and Hospital Epidemiology
Philadelphia Dermatologic Society
Philadelphia College of Physicians
American Society of Microbiology
Society of Pediatric Dermatology

Chapters, Reviews & Books

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2. *Laskas, J.J., Jr., and Leyden, J.J.: Punctate keratoderma. Arch Derm, 111(7):921, July, 1975.*

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4. *Leyden, J.J., McGinley, J.J., Mills, O.H., and Kligman, A.M.: Topical Antibiotics and Topical Antimicrobial Agents in Acne Therapy. In: Dermatology Symposium in Lund: Eds. J. Juhlin, H. Rossman, J.S.Strauss. Uppland Giafiska A.B. Uppala, 1980.*

5. *Kligman, A.M., and Leyden, J.J.: The Interaction of Fungi and Bacteria in the Pathogenesis of Athlete's Foot, in: Skin Microbiology: Relevance to Clinical Infection, Howard I. Maibach and Raza Aly (Eds.), published by Springer-Verlag, New York, NY, pp. 203-219, 1981.*

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7. *Leyden, J.J.: Topical antibiotics in the prophylaxis of experimental S. Aureus and S.Pygemes infections in humans in Skin Microbiology: Relevance to Clinical Infection: Howard I. Maibach and Raza Aly (Eds.); published by Springer-Verlag, New York, pages 269-274, 1981.*

8. *Leyden, J.J., and Kligman, A.M.: Antimicrobials, in Safety and Efficacy of Topical Drugs and Cosmetics, Albert Kligman and James Leyden (Eds.), published by Grune and Stratton, New York, NY, pp. 289-310, 1982.*

9. *Leyden, J.J., and Kligman, A.M.: Dandruff, in Safety and Efficacy of Topical Drugs and Cosmetics, Albert Kligman and James Leyden (Eds.), published by Grune and Stratton, New York, NY, pp. 182-288, 1982.*

10. *Leyden, J.J., and Kligman, A.M.: Wound Healing, in Safety and Efficacy of Topical Drugs and Cosmetics, Albert Kligman and James Leyden (Eds.), published by Grune and Stratton, New York, NY, pp. 275-280, 1982.*

11. *Leyden, J.J. and Kligman, A.M.: Axillary Odor and Deodorant Testing, in Safety and efficacy of Topical Drugs and Cosmetics, Albert Kligman and James Leyden (Eds.), published by Grune and Stratton, New York, NY, pp. 269-274, 1982.*

12. *Leyden, J.J.: Microbial Ecology in Interdigital "Athlete's Foot Infection," (in) Seminars in Dermatology, Arthur J. Rook and Howard I. Maibach (Eds.), published by /Thieme Stratton, New York, NY, pp. 149-152,1982.*

13. *Leyden, JJ.: Bacteriology of newborn skin, (in) Neonatal Skin, Howard I., Maibach, and E.K. Boisitis (ed.), published by Dekker Publishing House, New York, NY, 1982.*

14. *Leyden, J.J., McGinley, K.J., and Kligman, A.M.: Studies on the effect of shampoos on scalp lipids and bacteria, (in) Principles of Cosmetics for the Dermatologist, Phillip Frost and Steven N. Horowitz (eds.), published by the C.V. Mosby Company, St. Louis, pp. 16-27, 1982.*

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16. *Ruggieri, M.R., McGinley, K.J., Leyden, J.J., and Touchstone, J.C.: Reproducibility and Precision of Quantitation of Skin Surface Lipids by Thin Layer Chromatography. In: Quantitative Thin Layer Chromatography, Wiley Press, pp. 249-259, 1982.*

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18. *Leyden, J.J.: Pathophysiology of Cutaneous Bacterial Infections, Pathophysiology of Dermatologic Diseases. McGraw-Hill Book Company, New York, NY, 1984.*

19. *Leyden, J.J., McGinley, K.J., Webster, G.F.: Cutaneous Microbiology, Chapter 51.In: Biochemistry and Physiology of the Skin, (Ed.) L.H. Goldsmith Oxford University Press, Chap. 51, 1153-1165, 1983.*

20. *Dobson, R.L., Leyden, J.J., Noble, W.O., and Pries, J.D., Editors: Bactroban (Mupirocin), Excerpta Medica, 1985. (Not included in this binder).*

21. *Leyden, J.J.: Bacteriology of the human axilla: Relationship to axillary odor. Cosmetic Science and Technology, 1986.*

22. *Leyden, J.J., and Grove, G.L.: Skin Irritation, In: Transdermal Delivery Systems Cutaneous Toxicology. A.F. Kydomieus and B. Bermer (Eds). CRC Press Inc., 1987.*

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24. *Nordstrom, K.M., Tseng, S.C.G., and Leyden, J.J.: Effect of 13-Cis and all-Trans Retinoic Acid on the neural Lipids of the Meibomian Gland of the Rabbit. Acne and Related Disorders. Ronald Marks and Gerd Plewig (Eds.), published Martin Dunitz, London, England, pp. 179-182, 1989.*

25. *Vane, F.M., Chari, S.S., Shapiro, S.S., Nordstrom, K.M., and Leyden, J.J.: Comparison of the Plasma and Sebum Concentrations of the Arotinoid Ro 15-0778 and Isotretinoin (Accutane) in Acne Patients. Acne and Related Disorders. Ronald Marks and Gerd Plewig (Eds), published by Martin Dunitz, London, England, pp. 183-189, 1989.*

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31. *Leyden, J.J., and Aly R.: Tinea Pedis. [Review] [Journal Article, Review. Review, Tutorial] Seminars in Dermatology. 12(4):280-4, Dec. 1993.*

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34. *Leyden, J.J.Review-Handbook of Cosmetic Microbiology. Donald Orth, M.D. J.A.A.D. 32(2):301, Feb. 1995.*

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37. *Leyden,J.J., Marks,R.: Dermatologic Therapy in Current Practice. Martin Dunitz Ltd. 2001*

38. *Leyden,J.J.,Rawlins,A.:Dry Skin. Marcel Decker.2002*

Original Publications

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2. *Lantis, S., Leyden, J.J., Thew, M.D., and Heaton, C: Nevus sebaceous of Jadasshon, part of a new neurocutaneous syndrome? Arch Derm 98:117-123, 1968.*

3. *Fulton, J.E., Leyden, J.J., and Papa, C.M.: Treatment of vitiligo with topical methoxsalen and black light. Arch Derm 100:224-229, 1969.*

4. *Marples, R.R., Fulton, J.E., Leyden, J.J., and McGinley, K.J.: Effects of Antibiotics on the nasal flora in acne patients. Arch Derm 99:647-651, 1969.*

5. *Leyden, J.J., and Wood, M.: The half and half nail, an uremic onychopathy. Arch Derm 105(4):591-592, 1972.*

6. *Decherd, J., Mills, O.H., and Leyden, J.J.: Naevus comedonicus-treatment with retinoic acid. Br J Derm 86(5):529-529, 1972.*

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8. *Stein, K., Leyden, J.J., and Goldschmidt, H.: Localized acneiform eruption following cobalt irradiation. Br J Derm 87(3):274-279, 1972.*

9. *Leyden, J.J., Lockshin, N., and Kriebel, S.: The black keratinous cyst - a sign of hemochromatosis. Arch Derm 106(3):379-381, 1972.*

10. *Leyden, J.J., Spott, D.A., and Goldschmidt, H.: Diffuse and banded melanin pigmentation in nails. Arch Derm 105(4):548-550, 1972.*

11. *Leyden, J.J., Dechard, J. and Goldschmidt, H.: Exfoliative cytology in the diagnosis of psoriasis of nails. Cutis 10:701-704, 1972.*

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14. *Benett, R.G., Leyden, J.J., and Decherd, J.W.: The heroin ulcer. New Addition to the differential diagnosis of ulcers of the penis. Arch Derm 107(1):121-122, 1973.*

15. *Leyden, J.J., and Mills, O.H.: Cystic acne as a source of bleeding in hemophilia. Arch Derm 107:456-466, 1973.*

16. *Leyden, J.J., and Master, G.H.: Oral cavity pyogenic granuloma. Arch Derm 108(2):226-228, 1973.*

17. *Leyden, J.J. and Marples, R.R.: Ecological principles and antibiotic therapy in chronic dermatoses. Arch Derm 107(2):108-211, 1973.*

18. *Leyden, J.J., Marples, R.R.: Superinfection induced by antibiotics in familial benign chronic pemphigus. Acta Derm Venerol Suppl. 53(1):61-64, 1973.*

19. *Leyden, J.J., Marples, R.R., Mills, O.H., and Kligman, A.M.: Gram-negative folliculitis - complication of antibiotic therapy in acne vulgaris. Br J Derm 88(6):533-538, 1973.*

20. *Kligman, A.M., Mils, O.H., Leyden, J.J., and Fulton, J.E.: Postscript to vitamin A-acid therapy for acne vulgaris. Arch Derm 107(2):296, 1973.*

21. *Mills, O.H., Leyden, J.J., and Kligman, A.M.: Tretinoin treatment of steroid acne. Arch Derm 108(3):381-384, 1973.*

22. *Klein, A.W., Rudolph, R.I., and Leyden, J.J.: Telogen effluvium as a sign of Hodgkin's disease. Arch Derm 108(5):702-703, 1973.*

23. *Scott, R.W., Klein, A.W., and Leyden, J.J.: Acanthanosis Nigricans associates with a benign encephalopathy. Arch Derm 109(1):78-80, 1974.*

24. *Leyden, J.J.: Antibiotic usage in dermatological practice. Review Article: 24 Ref. Int J Dermatol 1974 Nov-Dec, 13(6):342-352.*

25. *Leyden, J.J., Mills, O.H., Kligman, A.M.: Cryoprobe treatment to Acne conglobata. BrJ Dermatol Mar 90(3):335-41, 1974.*

26. *Kligman, A.M., Mills, O.H., Jr., and Leyden, J.J.: Acne vulgaris: a treatable disease. Post Grad Med Feb 55(2):99-105, 1974.*

27. *Berger, B.J., Rudolph, R.I., and Leyden, J.J.: Letter: Transient acantholytic dermatosis. Arch Derm June 109(6):913, 1974.*

28. *Decherd, J., Leyden, J.J., Holtapple, J.J.: Facial Pyoderma gangrenosum in preceding ulcerative colitis. Cutis 14:208-210, 1974.*

29. *Rudolph, R.I., Schwartz, W., and Leyden, J.J.: Bitemporal Aplasia Cutis Congenita occurrence with other cutaneous abnormalities. Arch Derm 110(4):615-618, 1974.*

30. *Marples, R.R., Leyden, J.J., Stewart, R., Mills, O.H., and Kligman, A.M.: The Skin microflora in acne vulgaris. J Invest Derm 62(1):37-41, 1974.*

31. *Kligman, A.M., and Leyden, J.J.: Adverse effects of Fluorinated steroids applied to the face. J.A.M.A. 229(1):60-62, 1974.*

32. *Leyden, J.J., Marples, R.R., and Kligman, A.M.: Staphylococcus aureus in the lesions of atopic dermatitis. Br J Dermatol 90(5):525-530, 1974.*

33. *Klein, A., Burns, L., Leyden, J.J.: Rectal mucosa involvement in keratosis follicularis. Arch Derm 109(4):560-561, 1974.*

34. *Leyden, J.J., Marples, R.R., Mills, O.H., Kligman, A.M.: Tretinoin and antibiotic therapy in acne vulgaris. South Med 67(1):20-25, 1974.*

35. *Leyden, J.J.,, Thew, M., and Kligman, A.M.: Steroid Rosacea. Arch Derm 110(4):619-22, 1974.*

36. *Rudolph, R.I., Berger, B.J. and Leyden, J.J.: Efficacy of Physiatric Management of Linear Scleroderma. Arch Phys Med and Rehab 55(9):428-431, 1974.*

37. *Rudolph, R.I., Schwartz, W., and Leyden, J.J.: Treatment of Staphylococcal Toxic Epidermal Necrolysis. Arch Derm 110(4):559-562, 1974.*

38. *Kligman, A.M., Mills, O.H., McGinley, K.J., and Leyden, J.J.: Acne therapy with Tretinoin in combination with antibiotics. Acta Dermato Venereol 74:111-115, 1974.*

39. *Leyden, J.J., Kligman, A.M.: Aluminum chloride in the treatment of symptomatic "Athlete's foot." Arch Derm 111(8):1004-1010, 1974.*

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41. *Leyden, J.J., McGinley, K.J., Mills, O., and Kligman, A.M.: Age related changes in the resident bacterial flora of the human face. Journal Invest Dermatol 65(4):379-381, 1974.*

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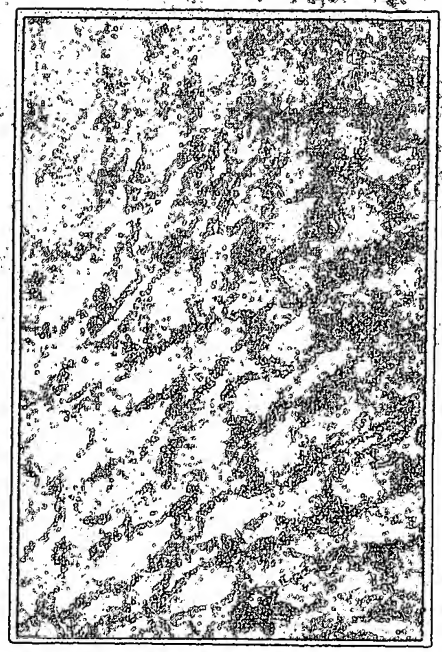
Volume I

Fitzpatrick's DERMATOLOGY in GENERAL MEDICINE



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sixth edition

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DERMATOLOGY IN GENERAL MEDICINE

SIXTH EDITION

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CHAPTER 124

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Seborrheic Dermatitis

Seborrheic dermatitis is a common chronic papulosquamous dermatosis that is usually easily recognized. It affects infants and adults and is often associated with increased sebum production (seborrhea) of the scalp and the sebaceous follicle-rich areas of the face and trunk. The affected skin is pink, edematous, and covered with yellow-brown scales and crusts. The disease varies from mild to severe, including psoriasiform or pityriasiform patterns and erythroderma.[1] Seborrheic dermatitis is one of the most common skin manifestations in patients with human immunodeficiency virus (HIV) infection.[2] Consequently, it is included in the spectrum of premonitory lesions and should be carefully evaluated in high-risk patients.

INCIDENCE

Seborrheic dermatitis has two age peaks, one in infancy within the first 3 months of life and the second around the fourth to the seventh decades of life. No data are available on the exact incidence of seborrheic dermatitis in infants, but the disorder is common. The disease in adults is believed to be more common than psoriasis, for example, affecting at least 3 to 5 percent of the population in the United States.[3] Men are affected more often than women in all age groups. There does not appear to be any racial predilection. Seborrheic dermatitis is found in up to 85 percent of patients with HIV infection.[2]

ETIOLOGY AND PATHOGENESIS

Although many theories abound, the cause of seborrheic dermatitis remains unknown.

Seborrhea

The disease is associated with oily-looking skin (seborrhea oleosa), although an increased sebum production cannot always be detected in these patients.[4] Even if seborrhea does provide a predisposition, seborrheic dermatitis is not a disease of the sebaceous glands. The high incidence of seborrheic dermatitis in newborns parallels the size and activity of the sebaceous glands at this age. It has been shown that newborns have large sebaceous glands with high sebum secretion rates similar to adults.[5] In childhood, sebum production and seborrheic dermatitis are closely connected. In adulthood, however, they are not, as the sebaceous gland activity peaks in early puberty and decades later seborrheic dermatitis may occur.

The sites of predilection—face, ears, scalp, and upper part of the trunk—are particularly rich in sebaceous follicles. Two diseases are prevalent in these regions: seborrheic dermatitis and acne. In patients with seborrheic dermatitis, the sebaceous glands are often particularly large on cross-sectional histologic specimens. In one study, skin surface lipids were not elevated but the lipid composition was characterized by an increased proportion of cholesterol, triglycerides, and paraffin, and a decrease in squalene, free fatty acids, and wax esters.[6] However, mild abnormalities in the skin surface lipids could well result from the ineffective keratinization, which is often demonstrable histopathologically. Seborrheic dermatitis seems to be more frequent in patients with parkinsonism, in whom sebum secretion is increased. Similarly, after reduction of sebum production induced by levodopa and by promestriene, seborrheic dermatitis may improve.

The synonym *eczéma flannelaire* stems from the idea that a retention of skin surface lipids by clothing and rubbing of the rough textiles on the skin—cotton (flannel), wool, or synthetic underwear in particular—promotes or aggravates seborrheic dermatitis.

Microbial Effects

Unna and Sabouraud, who were among the first to describe the disease, favored an etiology involving bacteria, yeasts, or both. This hypothesis has remained unsupported, although bacteria and yeast can be isolated in great quantities from affected skin sites.

In infancy, *Candida albicans* is often found in dermatitic skin lesions and in stool specimens. Although intracutaneous tests with candidin, positive agglutinating antibodies in serum, and positive lymphocyte-transformation tests in affected infants revealed sensitization to *C. albicans*, these observations cannot be convincingly linked to the pathogenesis.

Aerobic bacteria were recovered from the scalp of patients with seborrheic dermatitis (140,000 bacteria/cm^2 versus 280,000 in normal individuals and 250,000 in persons with dandruff). In contrast, *Staphylococcus aureus* was rarely seen in normal persons or those with dandruff. *Staphylococcus* was recovered in about 20 percent of patients with seborrheic dermatitis, accounting for an average of about 32 percent of the total skin flora.[7]

Propionibacterium acnes counts were low in patients with seborrheic dermatitis (7550 bacteria/cm^2 in those without dandruff). The small quantities of *P. acnes* in patients with seborrheic dermatitis may explain the low yield of free fatty acids from their skin surfaces.

The lipophilic yeast *Pityrosporum* is abundant in normal skin (504,000 organisms/cm^2 versus 922,000 in individuals with dandruff and 665,000 in patients with seborrheic dermatitis).[7] This organism has received particular attention in recent years. Some authors claim strong evidence in favor of a pathogenic role for these microbes, whereas others do not share this view. Their argument is that *Pityrosporum ovale* is not the causative organism, but is merely present in large numbers. In patients with pityriasis versicolor[8] and *Pityrosporum* folliculitis,[9] seborrheic dermatitis has been found in a higher percentage than expected. Clearing of seborrheic dermatitis by selenium sulfide and continued suppression of *P. ovale* with topical amphotericin B caused a

relapse of the disease on inflamed scalp skin.[10] In seborrheic dermatitis, both normal and high levels of serum antibodies against *P. ovale* have been demonstrated. A cell-mediated immune response to *P. ovale* has been found in normal individuals using *Pityrosporum* extracts in lymphocyte-transformation studies.[11] Overgrowth of *P. ovale* may lead to inflammation, either through introduction of yeast-derived metabolic products into the epidermis or as a result of the presence of yeast cells on the skin surface. The mechanism of production of inflammation would likely then be through Langerhans cell and T lymphocyte activation by *Pityrosporum* or its by-products. When *P. ovale* comes into contact with serum, it can activate complement via the direct and alternative pathways and this may play some part in the introduction of inflammation.[12] A possible role for this yeast in the pathogenesis of seborrheic dermatitis is supported by the fact that seborrheic dermatitis–like lesions have been shown to be reproducible in animal models by inoculation of *P. ovale*.[13]

Miscellaneous

DRUGS Several drugs have been reported to produce seborrheic dermatitis–like lesions, including arsenic, gold, methyldopa, cimetidine, and neuroleptics.

NEUROTRANSMITTER ABNORMALITIES Seborrheic dermatitis is often associated with a variety of neurologic abnormalities, pointing to a possible influence of the nervous system. These neurologic conditions include postencephalitic parkinsonism, epilepsy, supraorbital injury, facial paralysis, unilateral injury to the ganglion of Gasser, poliomyelitis, syringomyelia, and quadriplegia. Emotional stress seems to aggravate the disease; a high rate of seborrhea is reported among combat troops in times of war.

PHYSICAL FACTORS It has been suggested that cutaneous blood flow and skin temperature may be responsible for the distribution of seborrheic dermatitis.[14] Seasonal variations in temperature and humidity are related to the course of the disease. Low fall and winter temperatures and low humidity in centrally heated rooms are known to worsen the condition. Seborrheic dermatitis of the face was observed in 8 percent of 347 patients receiving PUVA therapy for psoriasis and occurred within a few days to 2 weeks after the beginning of treatment;[15] the patients had no previous history of facial psoriasis or seborrheic dermatitis. Lesions were avoided by masking the face during irradiation.

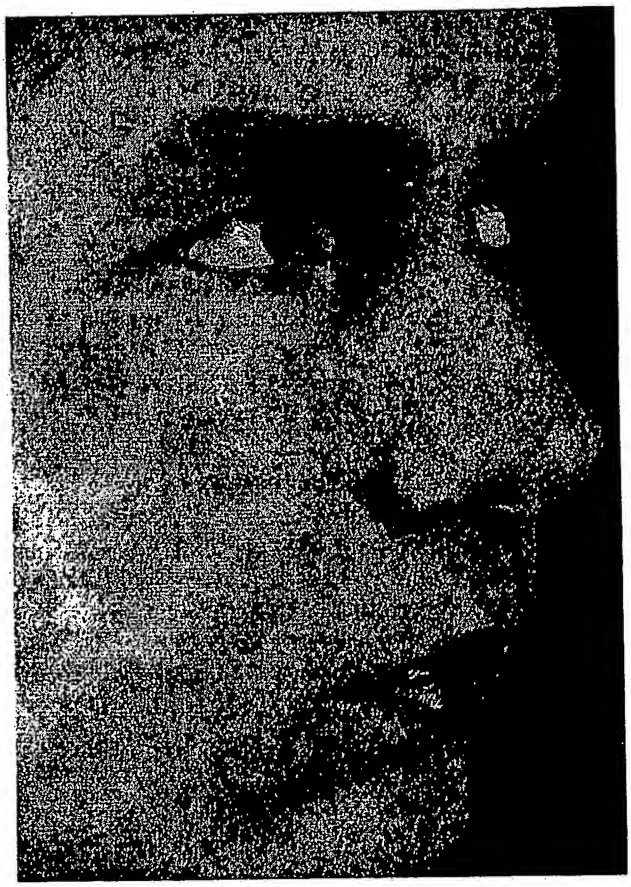
ABERRANT EPIDERMAL PROLIFERATION Epidermal proliferation is increased in seborrheic dermatitis, like psoriasis, explaining why cytostatic therapeutic modalities may improve the condition.[16]

NUTRITIONAL DISORDERS Zinc deficiency in patients with acrodermatitis enteropathica and acrodermatitis enteropathica–like conditions may be accompanied by dermatitis mimicking seborrheic dermatitis of the face. Seborrheic dermatitis is, however, not associated with zinc deficiency nor does it respond to supplementary zinc therapy. Seborrheic dermatitis in infancy may have a different pathogenesis. Biotin deficiency, whether secondary to a holocarboxylase deficiency or a biotinidase deficiency, and abnormal metabolism of essential fatty acids have been proposed as possible mechanisms.[17]

IMMUNODEFICIENCY AND SEBORRHEIC DERMATITIS

The development of seborrheic dermatitis either de novo or as a flare of preexisting disease also may serve as a clue to the presence of HIV infection. The first report of this association in 1984 was followed by observations from all parts of the world.[2] The expression of the disease differs in several aspects from its classical form seen in HIV seronegative individuals (Figs. 124-1 to 124-4): the distribution is extensive, severity is marked, and treatment often difficult (Fig. 124-5). Even the histopathologic changes differ somewhat from those seen in commonly encountered seborrheic dermatitis (Table 124-1).

FIGURE 124-1



Seborrheic dermatitis with involvement of nasolabial folds, cheeks, eyebrows, and nose.

The increased incidence and severity of seborrheic dermatitis in HIV seropositive individuals has led to speculation that unchecked growth of *Pityrosporum* in immunosuppressed patients is responsible. However, a study that compared quantitative *Pityrosporum* cultures in AIDS patients with and without seborrheic dermatitis failed to demonstrate increased yeast colonization in patients with seborrheic dermatitis.[18]

PSORIASIS AND SEBORRHEIC DERMATITIS

In patients with a psoriatic diathesis, particularly adults, seborrheic dermatitis is said to evolve into psoriasis. The term *sebopsoriasis* is sometimes used for these overlapping conditions. It should be used with caution because psoriasis, especially of the scalp, is clinically and histopathologically almost indistinguishable from seborrheic dermatitis.